

EXHIBIT U

Andrew N. Faes

From: Andrew N. Faes
Sent: Thursday, May 09, 2013 6:16 PM
To: Ben Watson; PCombs@tcspllc.com; MKABBASH@RIKER.com
Cc: Tom P. Cartmell; Bryan Aylstock; 'Renee Baggett'; Zonies, Joe; Greg Bentley; donna.jacobs@butlersnow.com; christy.jones@butlersnow.com
Subject: Production of documents prior to 30(b)(6) design deposition

Ben-

We have repeatedly asked for the production of any of the IFU's for the TVT "classic" that were in use prior to 01/16/2001 as well information regarding which were the final, in-use versions with effective in-use dates. Your most recent correspondence on the subject, dated 03-29-2013 stated that: "it is currently our understanding that a third party, Medscand Medical AB, manufactured this device prior to that date [01-16-2001] and that, as a result, Ethicon did not generate the IFU for this product for this time period. We are in the process of trying to locate a copy of the applicable IFU(s) and we will update you when we have more information regarding same." Given the fact that Ms. Susan Lin recently testified that changes to the IFU are part of the design control process, these documents are of particular importance to the 30(b)(6) deposition scheduled to begin on Wednesday of next week. As far as I know, we have still not been provided with in-use versions and dates for the TVT "classic" IFU prior to 01-16-2001 yet, nor have we received verification that production of documents Medscand Medical AB has been undertaken or is complete. Please let us know if we will have this production and information regarding in-use dates for the IFU prior to the start of the design 30(b)(6) deposition. If you think you will be unable to provide those documents prior to the deposition, we need to know that right away as well.

We also want to verify that production of the design history file on the TVT "classic" is complete as well prior to the start of this deposition. The Design history files indicate that there are numbers assigned to the Design History Files for the TVT "classic" which run from DH0263-DH0278, yet we have only been able to locate DH0268 and DH0269, and your responses and objections to our 30(b)(6) deposition notice also indicate that those are the only two original design history files which have been produced with regard to the TVT "classic." Can you please verify that the production of the TVT "classic" design history files is complete, and verify whether or not the apparent missing Design History Files numbered from DH0263-DH0267 and DH0270-DH0278 are applicable to the TVT "classic" or other responsive product as soon as possible? If you are not able to verify that production of the TVT "classic" Design History files is now complete, we need to know that prior to the scheduled deposition as well.

Additionally, I want to re-state our request from yesterday regarding Policy OP-650-011. We would like all final versions of this policy as well as corresponding in-use and approval dates identified and produced before the 30(b)(6) deposition that is to begin next Wednesday. We have identified numerous versions of this policy in the materials you have already produced to us, but have no way of identifying for certain which is the final in-use version, or the active dates for each version. Let us know if you cannot provide this before the design 30(b)(6) scheduled for next week right away. I had not received any kind of response to this yesterday, other than a response from Phil Combs indicating he had forwarded the request to "Le Clair" and I wanted to make sure it was received.

Thanks

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